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Animal Studies: Harmful or Beneficial?

The FDA released an article announcing the reduction of animal models. While advances in technology and modeling have shifted, it is important to understand both sides of the policy change. For decades, animal models have been a part of medical advances, while raising concerns about ethical responsibility and scientific authenticity. A balanced analysis shows that while animal models offer advantages in studying complex systems, they also have weaknesses that justify the FDA's alternative methods.

One strength of using animal models is their ability to replicate organism physiology. Unlike cell cultures, living animals have interacting organ systems, allowing researchers to study responses to specific diseases and treatment. Animal models mimic disease progress with their immune responses and drug metabolism in ways that isolated systems cannot (India D et al., 2022). This is important in industries, such as pharmacokinetics, where absorption, distribution, and metabolism must be researched across multiple biological systems before transferring to humans. There have been many lifesaving therapies, including but not limited to vaccines and surgical procedures due to animal research.

A second strength is the genetic and physiological similarity to humans. Laboratory species, specifically mice, share a lot of genetic homologies with humans. The development of knockout animal models has allowed researchers to study genetic mechanisms such as cancer, metabolic disorders, and psychiatric conditions. For example, animal models have given insight

into neurochemical pathways and brain circuitry that would be impossible to study in humans (Harro, Jaanus et al., 2018). This has made them valuable for understanding how diseases function.

Continuing from the second strength to the third, animal models allow for controlled experimental conditions. Variables such as diet, age and environmental exposure can be controlled in ways that are not promised in human populations. This control increases reproducibility and allows researchers to isolate biological variables. Regulatory agencies have relied on this consistency when evaluating safety and toxicity data before approving drugs for clinical trials (India D. et al,.).

Lastly, animal research gives the opportunity to test invasive procedures that would be frowned upon on humans. Not only are they able to test procedures, but they can look at the long-term effects. Surgical techniques and dose escalation studies can be evaluated for safety before being transferred into human medicine.

However, despite the strengths, there are weaknesses of animal models. One limitation is poor translation success. Many drugs that are considered safe in animals fail in human trials. There is similarity between some species and humans, but there are biological differences including a variation in immune response, metabolism, and gene regulation, reducing the reliability of extrapolating animal data directly to humans (Hartung, 2008). This gap is a critical point in animal research.

A second weakness involves the validity of certain behavioral and disease models. In psychiatric research, animal behaviors are used to model depression may not represent how a human may handle depression. Critics argue that behavioral tests lack validity and may

oversimplify human conditions (Harro, Jaanus et al., 2018). These concerns mainly focus on how accurately animal data reflects human pathology.

Third, selecting the right animal model is a problem itself. Not all species are suitable for every disease. Choosing the wrong one can led to misleading results and wasted resources (India D. et al., 2022). Another issue that presents itself is when there are a lot of available models. Having too many models can create different research outcomes, raising complications for researchers and interpreting and comparing data across studies.

The most common weakness in animal models is ethical considerations. Animal experimentation involves invasive procedures, induced disease states, and euthanasia. Scientific and societal concerns have led to the creation of the 3R's: reduction, refinement, and replacement. The 3R's encourages minimizing animal use and developing alternatives whenever possible (Hartung, 2008). There has been an increase in use of stem cell models, and advanced technological simulations reflecting a scientific movement toward methods that may improve human relevance while reducing ethical concerns.

In conclusion, animal models have played a huge role in biomedical history with organism experimenting, genetic manipulation, and controlled testing. However, there are limitations related to accuracy, model effectiveness, species differences and ethical concerns, promoting a reevaluation of their role in research. The FDA's decision to phase down reliance on animal models does not dismiss what they have accomplished in the past for human advancement, but to understand how to be better in the future.

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Straying Away from Animals

Biomedical research has started to shift away from animal testing by coming up with different approaches to non-animal testing, also called NAMs. Some of these methods use technology like 3D organoids and microfluidic organ-on-chip systems, which rely on human derived induced pluripotent stem cells, also known as iPSCs. There are also computational models and artificial intelligence that are beginning to grow, especially in toxicological research. All these approaches offer advantages over animal models, which often fail to represent human responses due to biological differences. However, even with these advancements, current NAMs still have challenges when it comes to replicating more complex processes such as organ interactions, tissue aging, and endocrine signaling.

Microfluidic organ-on-chip systems and 3D organoids use iPSCs to create realistic models for drug testing compared to animal models. iPSCs are adult cells turned into different types of specialized cells. This allows for researchers to grow human tissues, reflecting what happens in the human body. These cells form organoids, which are 3D structures that mimic human organs. Mimicking human structures provides a more realistic environment than convention two-dimensional cell cultures (Jodat et al., 2019). Organ-on-chip systems build on this by recreating important factors of human physiology, such as how cells interact and how tissues are organized, within a controlled environment. This is important because animal models often fail to predict human outcomes due to species-specific differences in physiology and

metabolism (Kwon, 2026). By using human-derived cells in systems, researchers can produce results that are relevant to human health. Overall, organoids and organ-on-chip technologies provide a more reliable approach to drug testing.

Computational models and artificial intelligence are becoming important tools for predicting toxicological outcomes using human-based data. Instead of relying on animal testing, these systems use large datasets. Large datasets can include chemical structures, lab experiments, and clinical data, to identify patterns linked to toxic effects. For example, machine learning models can predict how a compound will behave biologically based on molecular structure, allowing researchers to assess toxicity without the need for physical testing (Chang et al., 2025). This is useful when studying drug-induced liver injury, as an example, because these models can detect early warning signs that animal methods might miss. Another advantage is how fast and efficient these systems are. Researchers can use large numbers of data at once, which saves time and cost compared to animal testing. AI strengthens this process by simulating possible biological responses, even when data is limited.

Despite the progress of NAMs, they have limitations when it comes to replicating how the human body works. Many of these models focus on specific tissues or processes instead of capturing how multiple organ systems interact with each other. For example, while organoids and organ-on-chip systems can model individual organ functions, they lack key features like integrated vascular, immune, and endocrine systems, which are important for overall balance in the body. It is difficult to recreate more complex processes such as tissue aging, long-term drug exposure, and hormone signaling. Research has shown that recreating the full cellular diversity, density, and organization of native human tissues in vitro is still technically difficult, limiting the ability of these models to accurately predict long-term or systemic effects (Sohn, 2020). In

addition, there are technical challenges such as limited communication between modeled systems and difficulties scaling these technologies. Because of this, many current models only represent certain parts of human physiology rather than the full picture. NAMs cannot fully replace traditional models in all areas of research.

Overall, non-animal methods such as organoids, organ-on-chip systems and computational models are changing the way drug testing is done by providing more human-relevant and ethical alternatives to animal models. These approaches make it possible to predict how humans will respond to drugs by using human-derived cells and real biological data. Improvements in biomedical research will also help make the research process faster and more efficient, allowing researchers catch more and more issues earlier on. However, despite these advantages, there are still limitations. These limitations occur when it comes to replicating processes like organ interactions, tissue aging, and hormone signaling. Science improves every day, so despite these limitations, there is a chance researchers will stray away from animal modeling.

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